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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/665,314

09/19/2003

James J. Cali

02-482-B

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07/18/2008

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EXAMINER

CHUNG, SUSANNAH LEE

ART UNIT

PAPER NUMBER

1626

MAIL DATE

DELIVERY MODE

07/18/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/665,314	Applicant(s) CALI ET AL.	
	Examiner Susannah Chung	Art Unit 1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 June 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 132-134, 137-139 and 168-220 is/are pending in the application.
- 4a) Of the above claim(s) 190-220 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 132-134, 137-139 and 168-180 is/are rejected.
- 7) ☒ Claim(s) 181-189 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>6/19/08</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 132-134, 137-139, and 168-220 are pending in the instant application. Claims 1-131, 135-136, and 140-167 are canceled. Claims 132-134, 137-139, and 168-189 are pending in the instant action. Claims 190-220 drawn to a nonelected invention will be considered should allowable subject matter be found.

RCE

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after allowance or after an Office action under *Ex Parte Quayle*, 25 USPQ 74, 453 O.G. 213 (Comm'r Pat. 1935). Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 6/19/2008 has been entered.

Claim Rejections - 35 USC § 112, 1st paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 132-134, 137-139 and 168 are rejected under 35 U.S.C. 112, first paragraph, because the specification although enabling for a luciferin derivative is not enabled for all compounds “that is a substrate of a cytochrome P450 enzyme and a pro-substrate of a luciferase enzyme” without limitation, i.e. “a compound” reads on all compounds therefore a chemical structure of the compound should be inserted. The specification does not enable any person

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skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

As stated in MPEP 2164.01(a), “there are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is “undue.”

The factors to be considered when determining whether a disclosure meets the enablement requirement of 35 USC 112, first paragraph, were described in In re Wands, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) as:

1. the nature of the invention;
2. the breadth of the claims;
3. the state of the prior art;
4. the relative skill of those in the art;
5. the predictability or unpredictability of the art;
6. the amount of direction or guidance presented (by the inventor);
7. the presence or absence of working examples; and
8. the quantity of experimentation necessary (to make and/or use the invention).

The eight Wands factors are applied to Claims 132-134, 137-139, and 168 of the present invention below:

The nature of the invention is a process of making a metal complex.

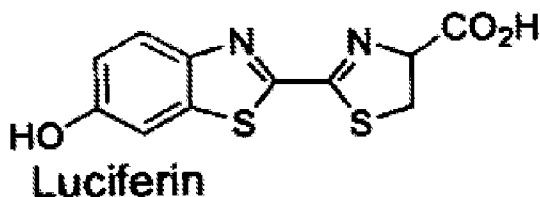
The breadth of the claims encompass all compounds, wherein there is no structural limitation other than it is a substrate of a cytochrome P450 enzyme and a pro-substrate of a luciferase enzyme. The applicable rule for interpreting the claims is that “each claim must be

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separately analyzed and given its broadest reasonable interpretation in light of and consistent with the written description.” See MPEP 2163(II)(1), citing In re Morris, 127 F.3d 1048, 1053-1054; 44 USPQ2d 1023, 1027 (Fed. Cir. 1997). In view of this rule, the compound reads on a large class of compounds and therefore it is broader than the enabling disclosure.

The state of the art of the instant class of compounds and compositions is that they are all

D-luciferin and D-luciferin derivatives.



The level of skill in the art (pharmaceutical chemists, physicians) would be high.

The compounds and compositions as currently claimed would read on a large number of compounds and compositions rendering the prior art unpredictable for making or using products as claimed on such a grand scale.

The specification in the present invention discloses derivatives of luciferin only.

The specification has no working examples of where the core compound is anything other than luciferin modified at the 6'-position.

Given the absence of direction or guidance (or working examples) in the specification for any of the extremely large number of compounds that would be encompassed by the claims, it would cause a skilled artisan an undue amount of experimentation to determine which products

are being claimed. Therefore, to overcome this rejection, the scope of the compound should be defined to those compounds with support in the specification.

Claim Rejections - 35 USC § 112, 2nd paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 132, 137, 138, 139, 169, 173, and 177 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims contain the trademark or trade name “luciferin,” “luciferol,” and “dehydroluciferin.” Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe a class of (4S)-4,5-dihydro-2-(6-hydroxy-benzothiazolyl)-4-thiazolecarboxylic acid compounds and, accordingly, the identification/description is indefinite.

Claims 132-134, 137-139, 168, 169, 171-173, 175-177, and 179-180 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The terms “luciferin,” “dehydroluciferin,” “luciferol,” and “pyrophosphatase” are indefinite. The metes

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and bounds of the terms are unknown and broader than the disclosure. Claims must stand alone to define the invention and incorporation into claims by express reference to the specification is not permitted. *Ex parte Fressola*, 27 USPQ 2d 1608.

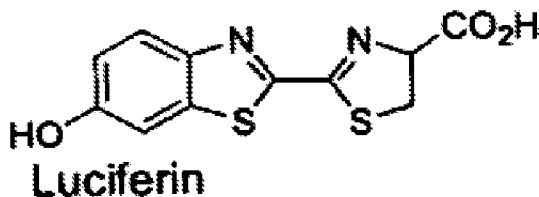
Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 132-134, 137-139, and 168-180 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description and enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The definition of the terms R1, R2, R3, R4, and R5 are not supported by the specification, claims or drawings. The instantly claimed invention is D-luciferin, which is defined in Figure 2

D-luciferin and D-luciferin derivatives.



as

or (4S)-4,5-dihydro-2-(6-

hydroxy-benzothiazolyl)-4-thiazolecarboxylic acid (See spec., page 3). D-luciferin's core

compound always contains an oxygen at the R1 position, carbon at the R2 and R3 positions, and

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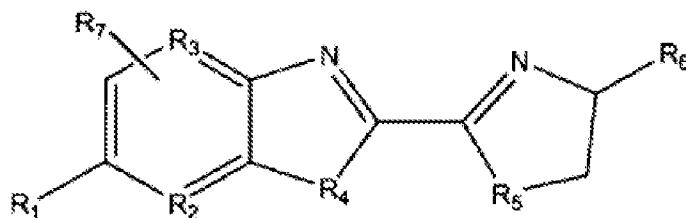
sulfur at the R4 and R5 positions. No other atom or functional group at those positions are supported by the instant specification, drawings, or claims. Applicant is invited to point out where in the original specification, claims or drawings the terms are supported and defined. If a proper definition cannot be found, then applicant may obviate this rejection by deleting the moieties that are not supported by the specification, claims and drawings.

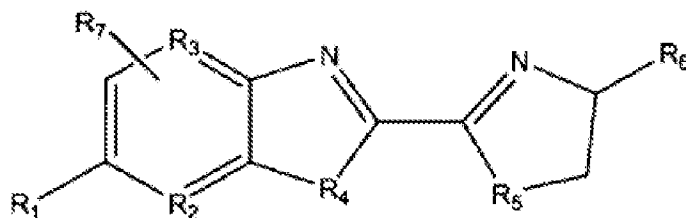
Claim Rejections - 35 USC § 112, 2nd paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

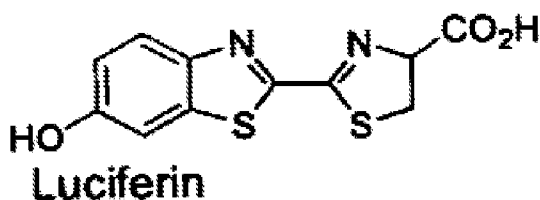
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 132-134, 137-139, and 168-180 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, Claim 135 is indefinite because the definition of “R1” is indefinite. Claim 135 is directed to a D-luciferin derivatives



having the formula , wherein R1 can be a plethora of different moieties ranging from hydrogen, hydroxy, alkoxy, cycloalkoxy, cycloalkylamino, etc... The definition of R1 is indefinite because the claim is directed to D-luciferin derivatives. D-luciferin is defined in Figure 2 as,

D-luciferin and D-luciferin derivatives.



or (4S)-4,5-dihydro-2-(6-hydroxy-benzothiazolyl)-4-thiazolecarboxylic acid (See spec., page 3). All of the D-luciferin derivatives in Figure 2 and the specification contain an oxygen atom at the 6' position. Therefore, the definition of R1 must contain oxygen and cannot be substituents such as hydrogen alone.

Obviousness Double Patenting

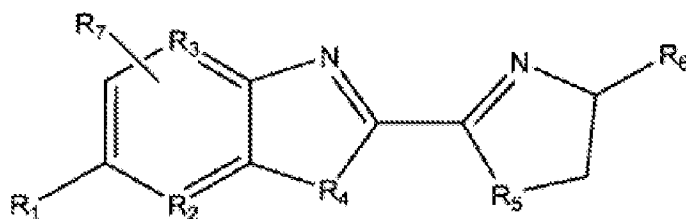
The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

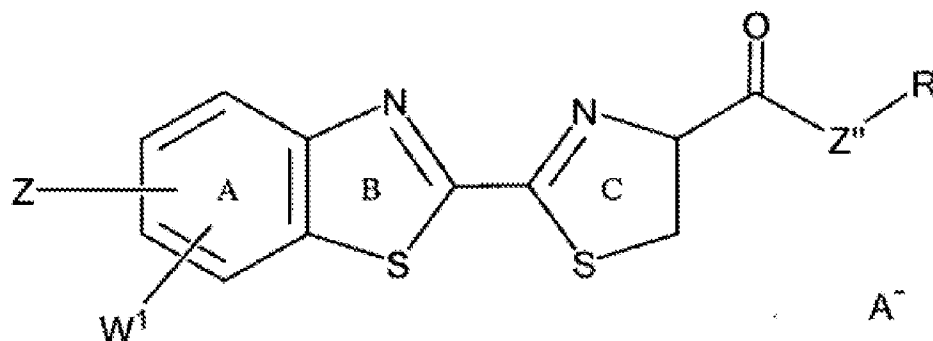
Claims 132-142 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-24, 68-71, and 91 of copending U.S. Pat. Appl. No. 11/444,145. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

Applicants instant elected invention discloses the compounds and compositions of



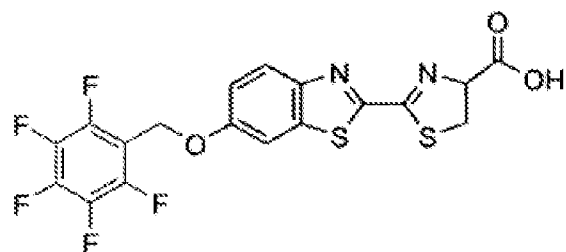
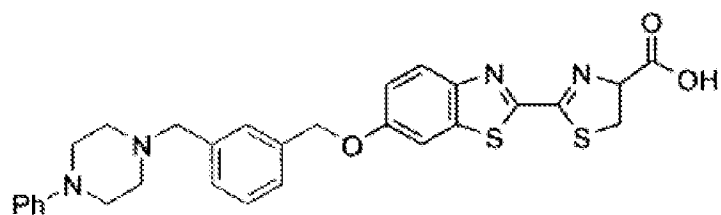
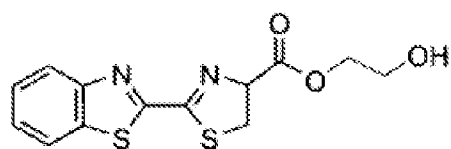
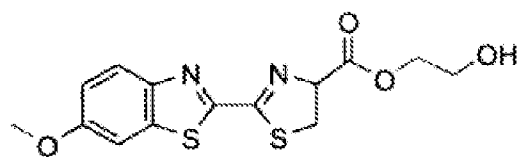
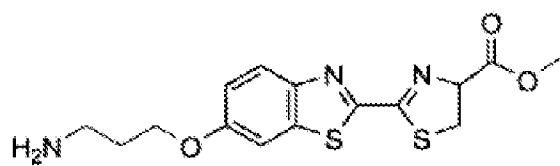
formula, , wherein R1 is preferably an oxygen containing functional group, R2 and R3 are carbon, R4 and R5 are sulfur, and R6 is CH₂OH or COR₁₁.

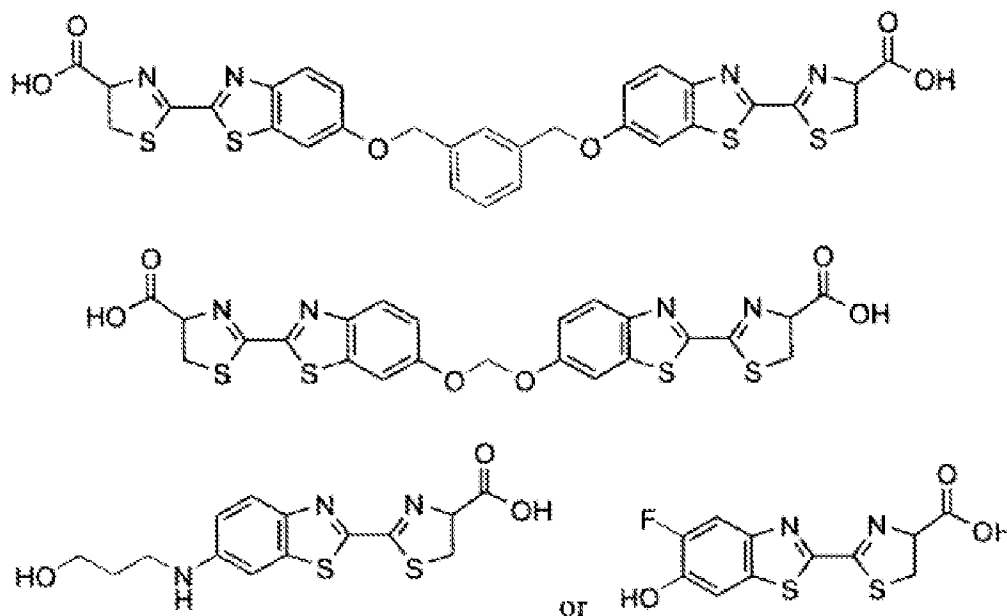
Co-pending application No. 11/444,145 claims the compound of formula (IIA),



preferred species in Claim 91:

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The difference between co-pending application no. 11/444,145 and the instant application is R1. In the co-pending application R1 is oxygen and nitrogen substituted moieties. In the instant application R1 can only be oxygen substituted moieties.

One skilled in the art would have found the claimed compounds *prima facie* obvious over the co-pending application because the instantly claimed compounds fall within the claims of the co-pending application and the preferred species for the variables are the same, i.e. oxygen substituted moieties. Furthermore, the co-pending application teaches one of ordinary skill in the art how to create the compounds claimed in the instant application. Given the overlapping preferred embodiments and the specific embodiments listed in the claims, one of ordinary skill in the art would be motivated to produce the species common to the applications. The motivation to make the claimed compounds derives from the expectation that structurally similar compounds would possess similar activity. Both the instantly claimed compounds and the compounds of the co-pending applications are used as markers. Although, the conflicting claims

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are not identical, they are not patentably distinct from each other because applicant's instantly claimed invention is disclosed in the co-pending application. Therefore, one skilled in the art would have found the variations obvious when faced with the co-pending application because the compounds are used for the same purpose so one skilled in the art would expect similar properties and results.

This is a provisional rejection and should all other issues be resolved, this rejection will be withdrawn at that point in time.

Objections

Claims 133, 170, 174, and 178 are objected to under 37 CFR 1.75 as being a substantial duplicate of claims from which they depend, i.e. claims 132, 169, 173, and 177. The claims state that they are composition claims, but the claim only contains one compound. A composition claim contains a minimum of two elements, which is lacking in the instant claims. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Deletion of the claims will overcome this rejection.

Claims 181-189 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susannah Chung whose telephone number is (571) 272-6098. The examiner can normally be reached on M-F, 8am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on (571) 272-0699. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/REI-TSANG SHIAO /
Primary Examiner, Art Unit 1626

Susannah Chung, July 17, 2008